UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH DAKOTA
SOUTHERN DIVISION

PAUL SCHILF and CYNTHIA SCHILF, as special administrators for the ESTATE OF PETER RAYMOND SCHILF, Deceased and PAUL SCHILF and CYNTHIA SCHILF, Individually, Plaintiffs,	)	
vs.	)	No. 4:07-cv-04015-LLP
ELI LILLY AND COMPANY and, QUINTILES TRANSNATIONAL CORPORATION, Defendants.	)	

PLAINTIFFS' FIRST AMENDED COMPLAINT

By Order of the Court, in accordance with Rule 15, Fed.R.Civ.P., Plaintiffs Paul and Cynthia Schilf file their First Amended Complaint, and for cause of action against Defendants Eli Lilly and Company and Quintiles Transnational Corporation would show the Court the following:

Nature of the Case

1. This is a South Dakota diversity/removal, products liability, wrongful death and survival case arising out of the tragic death of Plaintiffs' son, Peter Schilf, on or about December 24, 2004. At the time of his death, 16-year old Peter had just begun taking a psychoactive antidepressant medication called Cymbalta, which was

designed by, and is manufactured, promoted, and distributed by Defendant Eli Lilly and Company. Cymbalta is marketed by both Lilly and its co-Defendant Quintiles. The medication was provided in sample packet form from family physician Dr. Richard Briggs.

Parties

2. Plaintiffs in this action are Peter's parents, Paul Schilf and Cynthia Schilf. They bring this action individually and on behalf of their son's estate. The Schilfs are residents of Brandon, South Dakota.

On January 25, 2006, the Schilfs were appointed as Special Administrators for the Estate of Peter Raymond Schilf, Deceased, in Circuit Court, Second Judicial Circuit, County of Minnehaha, the Honorable Kathleen K. Caldwell, Circuit Court Judge, presiding. The Schilfs are beneficiaries of this action pursuant to SDCL 21-5-5, *et. seq.*

3. Defendant Eli Lilly and Company (hereinafter referred to as "Eli Lilly" or simply "Lilly") is an Indiana corporation with its headquarters in Indianapolis, Indiana. It is engaged in the business of research, development, testing, manufacturing, promoting, distributing, marketing, and selling pharmaceutical drugs, including the drug Cymbalta (generically known as duloxetine hydrochloride), which was distributed throughout South Dakota. Eli Lilly is authorized and licensed to do

business in the State of South Dakota. It has appeared and answered herein. Indeed, Lilly removed this case to federal court.

4. Quintiles Transnational Corporation [hereinafter "Quintiles"] is a foreign corporation with corporate headquarters at P. O. Box 13979, Research Triangle Park, North Carolina, 27709, (street address for deliveries - 4709 Durham, North Carolina 27703). On its company website it touts itself as "the global leader in pharmaceutical services." Quintiles also transacts business in the State of South Dakota and is amenable to the Court's jurisdiction.

Jurisdiction and Venue

5. This case was originally filed in state court. At the time of its filing, there was a non-diverse defendant, who has, since then, been dismissed. After that dismissal the citizenship of the parties was diverse. Accordingly, Lilly removed the case to this Court. Because the newly added Defendant Quintiles is also a foreign corporation, the parties still have diversity of citizenship. Jurisdiction is proper under 28 U.S.C. §1332 and 1346.

6. The Schilfs reside in this District and Peter died in this district. Venue is proper here. 28 U.S.C. §1391.

Facts

This suit has been necessitated by virtue of the following facts, pleaded here with some specificity, in order to apprise the Court and Defendants of the allegations and to narrow issues of dispute via a proper Rule 8 answer.

The Antidepressant Era – From Fluoxetine to Duloxetine

7. In 1988 Eli Lilly launched the first blockbuster, modern antidepressant. The trade name was Prozac; the generic name was "fluoxetine." One of the supposed advantages of this medication, touted heavily by Lilly in its marketing, was its selectivity. By this was meant that its presumed mode of action was via the inhibition of the "reuptake" of the neurotransmitter serotonin. Thus, this drug and its subsequent look-alike cousins were commonly called "Selective Serotonin Reuptake Inhibitors," or "SSRI's" for short.

8. In that same year, Lilly researcher David T. Wong (one of the inventors of Prozac) created another drug. Initially labeled as LY227942, it came to be known generically as "duloxetine." One of the key differences for this drug was that, unlike Prozac, it operated on two different brain chemicals, or neurotransmitters, *i.e.,* both serotonin and norepinephrine. Drugs that do this are sometimes called "Serotonin Norepinephrine Reuptake Inhibitors" or "SNRI's" for short. At the present time, there are only two being marketed in this country, *i.e.,* Wyeth's Effexor and Lilly's Cymbalta (generically known as "duloxetine").

9. In November of 2001, with patent protection for Prozac waning, Lilly filed a New Drug Application seeking FDA approval to market duloxetine as an antidepressant. In this country, and elsewhere, it also conducted clinical trials and sought regulatory approval for other "indications," including stress urinary incontinence, fibromyalgia, and, most recently "generalized anxiety disorder" (NDA approved on February 26, 2007).

Suicidality in the Duloxetine Clinical Trials

10. There were several suicide attempts, and at least four completed suicides, in Lilly's clinical trials with duloxetine. On information and belief it is alleged that, in one or more of these instances, Lilly's investigators and agents made "causality" or "relatedness" assessments in which they concluded that the drug was either probably or definitely related to the suicide or suicide attempt. One of the completed suicides was Traci Johnson, a 19-year old Bible college student who, on February 7, 2004, while participating in a Lilly sponsored trial of duloxetine for stress urinary incontinence, hanged herself in Lilly's dormitory in Indianapolis. One of the exclusion criteria for this study protocol was that the patients in the study could not be depressed.

11. Lilly failed to apprise the prescribing physicians, pharmacists, and the public about these suicides and assessments. Rather, to the contrary, it did exactly the opposite, claiming in the class wide portion of the "**BLACK BOX**" labeling for

Cymbalta that "No suicides occurred in these trials." While technically true that no suicides occurred in the trials of the other antidepressant medications referenced in the FDA mandated pooled studies, as applied to Cymbalta this information is grossly misleading, incomplete, and, indeed, downright deceitful, because, as noted above, completed suicides did occur in the duloxetine clinical trials.

The Lilly/Quintiles "Strategic Partnership"

12. On or about July 18, 2002, while regulatory approval for Cymbalta was still pending before the FDA, Lilly and Quintiles entered into a "strategic partnership" to "commercialize" Cymbalta in the United States. Under the terms of that agreement, Lilly's own sales force was to be augmented with more than 500 sales representatives from Quintiles' "Innovex" group. The Innovex group was tasked to focus on primary care physicians. *See* www.innovex.com. Therefore, on information and belief, it is alleged that one or more of the sales representatives who called on Dr. Briggs and left samples of Cymbalta was, in actuality, an Innovex rep.

Direct-to-Consumer Marketing of Cymbalta

13. The FDA approved Cymbalta in August of 2004, and Lilly and Quintiles immediately launched the drug. They marketed the drug, *inter alia*, through massive "direct-to-consumer" advertising, by advertising in professional journals, by means of its own website, www.cymbalta.com, and also, as noted above, via its comarketing agreement with the "Innovex" division of Quintiles Transnational Corporation, by

sales calls on doctors. The sales representatives handed out lots of free sample packs of Cymbalta, thereby encouraging physicians like Dr. Briggs to start using it on patients.

14. One of the reasons that pharmaceutical companies expend great resources to market their drugs directly to consumers is that such promotional activities work. Industry studies show that approximately 84% of the time that a patients "asks his doctor" about a specific brand name drug, the patient receives a prescription for that drug from the doctor. Thus, in its marketing activities Lilly tries to bypass the independent, professional judgment of the so-called "learned intermediary."[1]

Suicidality – September 2004

15. Meanwhile, in September 2004, a storm which had been brewing for years came to a head. Beginning in February of 1990, and continuing for years thereafter, there had been considerable debate in the scientific literature and in the media concerning the potential association between serotonergic antidepressants like

[1] Lilly has pled the "learned intermediary" doctrine as an affirmative defense and announced its intention to seek summary judgment on the basis of this defense. Because no South Dakota state court has ever adopted this common law modification of the duty to warn, this Court will have to make an Erie prediction on this issue. Given the unique facts of this case, as set forth above, it is likely that, when confronted with the issue, the South Dakota Supreme Court will decide, as the West Virginia Supreme Court recently did, *State ex rel. Johnson & Johnson Corp. v. Karl*, 2007 WL 1888777 (W.Va. June 27, 2007) to reject the doctrine. Pleading alternatively, if South Dakota does accept this affirmative defense, it is likely that it will adopt the entirety of that defense, as recently set forth in RESTATEMENT (THIRD) OF TORTS, §6(d).

Prozac and suicidality. In September 2004, two joint FDA Advisory Panels concluded that "causality has been established" regarding pediatric suicidality and recommended **BLACK BOX** warnings to physicians and express, *written*, lay-worded warnings about pediatric suicidality for patients.

16. In October, 2004 the FDA issued a warning that "Antidepressants increase the risk of suicidal thinking and behavior (suicidality) in children and adolescents with MDD [major depressive disorder] and other psychiatric disorders." The FDA stated that "[a]nyone considering the use of an antidepressant in a child or adolescent for any clinical use must balance the risk of increased suicidality with the clinical need." The agency also issued letters to manufacturers of all antidepressant medications, including Cymbalta, to add a "**BLACK BOX**" warning describing the increased risk of suicidality in children and adolescents given antidepressant medications.

Lilly/Quintiles Fail to Warn

17. Lilly could have asked the FDA to put a **BLACK BOX** warning on the Cymbalta label from the get-go, but it did not do so. Indeed, on information and belief it is alleged that Lilly has never asked the FDA for permission to implement any warning about any potential association between Cymbalta and suicide or its precursor conditions, and that the FDA has never prohibited Lilly from implementing

any such warning and never threatened to sue Lilly for "misbranding" regarding same.

18. Under the governing federal regulations, Lilly could have also added or strengthened a warning, or, indeed, even a contraindication for pediatric patients, on its own, *i.e.,* without prior FDA approval. Again, however, it did not do so.

19. Lilly could have also issued a "Dear Doctor" letter about the risks of pediatric suicidality, as its chief competitor, Wyeth, the manufacturer of the only other SNRI drug on the market had done on August 22, 2003. These letters are not part of "labeling" and do not require FDA approval. It is one way effectively to communicate serious, potentially lethal risks, to prescribing physicians. Lilly chose not to do this either.

20. Both Lilly and Quintiles could, and should, have made sure that, from inception, all of their sales representatives were trained to emphasize the suicide risk – particularly for pediatric patients like Peter Schilf – in their sales calls to physicians. But they did not do that either.

21. Finally, it is significant that, as noted above, the September 2004 panel also recommended that **patients** receive warnings themselves, not only as part of the informed consent process from their doctors, but also by means of a Patient Medication Guide, which would be directly distributed to them by the pharmacy which dispensed the medication. Lilly was aware of this recommendation. It could

and should have taken steps to make *sure* than any professional samples of Cymbalta which were left with doctors had medication guides which included a suicide warning, especially for pediatric patients. But it did not do this either.

Misrepresentations in Marketing

22. What Defendants did instead of warning was to issue aggressive advertising which touted the benefits of Cymbalta, while downplaying or ignoring the risk. For example, in November of 2004, Lilly published several journal ads promoting Cymbalta. Subsequently, on or about September 9, 2005, the FDA's Division of Drug Marketing, Advertising and Communications (DDMAC), which monitors drug companies' marketing and promotional activities, warned Lilly that these ads were "false and misleading" because they "fail to disclose any of these risks within the main parts of the ads." One of the risks that the FDA noted was the risk of suicide!

23. On information and belief it is alleged that the "slim jims" and other promotional materials which the Lilly and Quintiles representatives were using to "detail" Cymbalta to prescribing physicians like Dr. Briggs, also contained similar misrepresentations.

24. Physicians necessarily have to rely on companies like Lilly and Quintiles to provide them with complete, accurate, information about *both* the risks and benefits of drugs like Cymbalta.

25. The promotional activities for Cymbalta have been a major success for both Lilly and Quintiles.

Suicidality – 2005 and Beyond

26. Since the Fall of 2004, both the scientific literature and a series of regulatory edicts from the FDA have continued to strengthen the association between serotonergic drugs like Cymbalta and an increased risk of suicidality. The FDA-recommended **BLACK BOX** warnings were finally implemented in the Spring of 2005. A May 2005 FDA advisory quantified the risk of increased suicidality for pediatric patients taking Cymbalta as "1 in 50."

27. In December of 2006, two Lilly scientists, in collaboration with a group from Harvard, published a peer-reviewed paper which candidly acknowledges that there probably is, indeed, a "small vulnerable subpopulation" of patients who are at risk for Prozac-induced suicidality: "Even interventions which help the majority of patients may be associated with worsening in a small subset." Significantly, the paper identified the time period of greatest risk:

> Consistent with a previous analysis of suicidal behavior, the majority of new [Suicidal Ideation] emerged within the first 4 weeks, with the greatest incidence in the first week. This result suggests that the initial 4-week treatment period is one where vigilance is particularly important.

The admission underscores the fact that the drug manufacturer "has reason to know that" even *with* timely and adequate warnings – which were not provided in this case

– "health-care providers will not be in a position to reduce the risks of harm." RESTATEMENT (THIRD) OF TORTS, §6(d)(2). This militates in favor of a duty to warn patients directly. *Id*.

28. In the Spring of 2007, based on its further "reclassification" of the drug makers' suicidality data, the FDA extended the **BLACK BOX** warnings to young adults, ages 18-24.

29. Significantly, in its various writings the FDA has acknowledged that certain precursor conditions, associated with the use of these drugs, constitute the "biologically plausible" pathway from drugs to suicidality. These include a constellation of symptoms described as the "activation syndrome" and other conditions. Significantly, Lilly was aware from a peer-reviewed journal article in 1993, about all of these precursors.

Peter Schilf's Prescription for Cymbalta

30. Peter Schilf was a fine, extremely intelligent young man. His hobbies included beekeeping and operating a ham radio.

31. On or about November 24, 2004, Peter presented to an after hours clinic complaining of depression. He was referred for follow-up to his family physician, Dr. Briggs. Two days later, Dr. Briggs saw Peter and diagnosed him with depression. People who have depression are, *ipso facto,* at greater risk for suicide. They – and their physicians – more than anyone, need complete, accurate, explicit warnings.

32. Dr. Briggs started Peter on 30 milligrams of Cymbalta with the dosage increased to 60 milligrams after the first week.

33. In spite of the fact that he had received absolutely no warnings or instructions whatsoever from either Lilly or Quintiles regarding the risk of pediatric suicidality, Dr. Briggs was apparently aware of the recent FDA recommendation for a class wide suicide warning. But he was *unaware* that suicides had actually occurred during the Cymbalta trials. Indeed, in his deposition in this case he was asked to write out the warning which he claims to have given the Schilfs about the risk of suicide. Tellingly, he writes:

> Warnings. FDA has indicated that recent studies have been evaluated and as a result there may be an increased association with antidepressants and suicide ideations and gestures. No completed suicides occurred during the clinical trials. Cymbalta was not specifically studied.

Briggs' Deposition Ex. 1.

34. This warning, even if given, demonstrates the degree to which Lilly and Quintiles had failed to educate this "learned intermediary." Contrary to his impression, Cymbalta had been studied. Contrary to his impression, there **were** completed suicides "during the clinical trials" with Cymbalta. One was a 19-year old non-depressed healthy volunteer in a stress urinary incontinence study. Dr. Briggs was not made aware of Traci Johnson's death. Nor was he aware of the other suicide deaths in Lilly's clinical trials, or Lilly's causality assessments regarding same. Nor,

as well, was he aware of the fact that the FDA had already recommended that patients receive written warnings about the increased risk of pediatric suicidality.

35. Without full disclosure from Lilly and Quintiles, and lacking candid knowledge about the nature and extent of the risk, Dr. Briggs was not able to balance the risks and benefits and was not able to fully inform his patient and his parents before getting their consent.

36. Dr. Briggs gave Peter samples of the drug to last for four weeks and asked him to make a follow-up appointment in three weeks. The samples were in sealed bottles but the bottles were not in boxes, nor were there any labels, warnings, instructions, or package inserts. Peter returned for a follow-up appointment on December 17, 2004. Dr. Briggs continued Peter on Cymbalta and instructed him to return in one month for a recheck.

37. On December 24, 2004, approximately one month after Peter started taking Cymbalta, he committed suicide by self-inflicted gunshot wound.

38. Peter is survived by his parents, Paul Schilf and Cynthia Schilf; and his sister Leah F. Schilf, a minor.

Legal Theories - Causes of Action

All of the foregoing facts are cognizable under one or more of the following legal theories, recognized by South Dakota law.

39. FIRST: Negligence. Lilly has been negligent in a variety of respects, including failure to test specifically regarding the potential association between duloxetine and suicidality and its precursors, failure to warn, failure to recommend patient screening mechanisms,[2] negligent misrepresentations, overpromotion, and negligent infliction of emotional distress. Quintiles' marketing efforts were similarly unreasonable or negligent. Both Defendants' negligence was a proximate cause of Peter's injuries and death.

40. SECOND. Strict Tort Liability. South Dakota adopted the RESTATEMENT (SECOND) OF TORTS, §402A in 1973, in order (a) to protect the public, and (b) to ensure that the damages resulting from defective products are borne by those who market the product. Cymbalta is "defective" and "unreasonably dangerous," both as "designed" and as "marketed" within the meaning of the RESTATEMENT and the case law, and this condition was also a legal cause of Peter's injuries and death. Both Defendants are liable, jointly and severally, under this theory.

41. THIRD. Misrepresentation. Although no South Dakota state or federal court has yet addressed the issue, it is likely that, when they do, they will embrace the strict liability tort of misrepresentation, as set forth in RESTATEMENT (SECOND) OF

[2] Approximately 8-12% of the population have genetic anomalies which impair their bodies' abilities to metabolize these drugs. Lilly has never recommended that patients be screened for these anomalies before being put on these drugs.

TORTS §402B. Defendants' misrepresentations to Dr. Briggs were also a proximate or legal cause of Peter's injuries and death.

42. FOURTH. Deceit. A deceit within the meaning of SDCL §20-10-1 is either: (a) The suggestion, as a fact, of that which is not true, by one who does not believe it to be true; (b) The assertion, as a fact, of that which is not true, by one who has no reasonable ground for believing it to be true; (c) The suppression of a fact by one who is bound to disclose it, or who gives information or other facts which are likely to mislead for want of communication of that fact; or (d) A promise made without any intention of performing." Defendants' suppression of information concerning completed suicides during the Cymbalta clinical trials is certainly deceitful within the meaning of the statute. It, too, was a proximate cause of Peter's injuries and death.

43. FIFTH. Breach of Warranty. Lilly has breached both the express and implied warranties and such breaches are also a proximate cause of Peter's injuries and death.

Damages

44. Wrongful Death. Plaintiffs seek all recoverable damages under the South Dakota Wrongful Death Act. SDCL §21-5-1, *et. seq.* Specifically, as a result of Defendants' tortious activities and defective product, the Schilfs have been deprived of their son's love, support, comfort, aid, counsel, society, companionship,

guidance and services, and have incurred expenses, including burial and funeral costs. They sue to recover all elements of damage. The amount is in the millions of dollars and will be particularized on request.

45. Survival Damages. The Estate seeks damages for Peter's conscious pain, mental anguish, suffering, and despair from the time he first ingested Cymbalta up to the time of his death in an amount to be determined by the Jury.

46. Punitive Damages. Lilly's conduct was in willful, wanton, and conscious disregard for the rights of Plaintiffs, for which punitive damages are recoverable pursuant to SDCL § 21-3-2. However, in view of the *Erie* predictions[3] of federal courts in this State, punitive damages are not sought for Peter's wrongful death, but are sought with regard to the survival claim for his personal injuries.

47. Costs of Court and Interest. Prejudgment interest is appropriate on the economic damages, in accordance with SDCL §21-1-13.1; and post-judgment interest on the entire award.

Jury Demand

48. Plaintiffs hereby invoke their constitutional right to trial by jury.

[3] *Compare Sheesley v. Cessna Aircraft Co.*, 2006 DSD 6, 2006 US Dist Lexis 27133 * 76; and *Bethel v. Janis*, 597 F.Supp. 56 (D.S.D. 1984), *with Ammann v. Massey-Ferguson, Ltd.*, 933 F.Supp. 840 (D.S.D. 1996).

Wherefore, Plaintiffs pray that, following the trial, they have judgment of and against Defendants Eli Lilly and Quintiles for the remedies sought herein, and such other and further relief as shall be appropriate under the law and the facts.

Respectfully submitted,

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Certificate of Service

I certify that on this 13th day of November, 2007, Plaintiffs' First Amended Complaint has been electronically filed with the Clerk using the CM/ECF system, which will automatically send email notifications of such filing to the following attorneys of record:

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